PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 1/00, 29/00, 31/00 — A1

(11) International Publication Number: **WO 00/04942**

(43) International Publication Date: 3 February 2000 (03.02.00)

(21) International Application Number: PCT/US99/10180

(22) International Filing Date: 10 May 1999 (10.05.99)

(30) Priority Data:
09/120,535 21 July 1998 (21.07.98) US

(71) Applicant: HEARTPORT, INC. [US/US]; 700 Bay Road, Redwood City, CA 94063 (US).

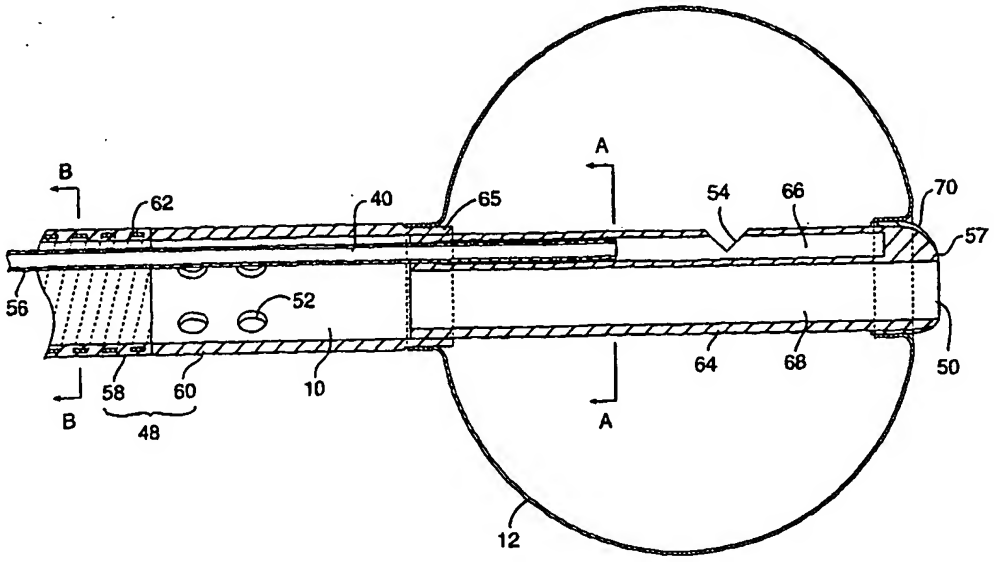
(72) Inventors: KELLY, Amy, C.; 2714 Hyde Street, San Fracisco, CA 94109 (US). HUNDERTMARK, Ronald, R.; 823 9th Avenue, San Mateo, CA 94402 (US). SOO HOO, John, K.; 2923 Meridien Circle, Union City, CA 94587 (US). MATA, Gilbert, Jr.; 2704 Melanie Court, Ceres, CA 95307 (US).

(74) Agents: GRAINGER, Jeffry, J. et al.; Heartport, Inc., 700 Bay Road, Redwood City, CA 94063 (US).

(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: MULTI-LUMEN CATHETERS AND METHODS OF USE AND MANUFACTURE



(57) Abstract

This invention is a multi-lumen catheter having a main lumen (10), and an inflation lumen (40). The inflation lumen (40) passes through the main lumen (10), and is not connected to the main lumen (10) for a distance of at least three inches. The multi-lumen catheter (8) may be used to vent blood from the pulmonary artery, and direct the blood to a bypass system (6). The multi-lumen catheter (8) may also be used as an aortic occlusion catheter which occludes the ascending aorta and delivering cardio-plegia fluid to arrest the patient's heart in preparation for surgery on the heart, and circulatory system.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

MULTI-LUMEN CATHETERS AND METHODS OF USE AND MANUFACTURE

BACKGROUND OF THE INVENTION

The present invention relates to multi-lumen catheters for medical and diagnostic procedures. Such procedures include cardiovascular, neurosurgical, pulmonary and other interventional procedures, including repair or replacement of aortic, mitral and other heart valves, repair of septal defects, congenital defect repairs, pulmonary thrombectomy, coronary artery bypass grafting, angioplasty, atherectomy, treatment of aneurysms, electrophysiological mapping and ablation, neurovascular procedures, general anesthesia, and cardiopulmonary bypass.

Various multi-lumen catheters are disclosed in U.S. Patent No. 5,584,803 to Stevens et al. and U.S. Patent No. 5,682,906 to Sterman et al. which are hereby incorporated by reference. These catheters are useful in arresting a patient's heart and maintaining the patient on bypass support while the heart is arrested. Once the patient's heart is arrested and the patient is on bypass support, the patient is ready for surgery on the heart, great vessels and other portions of the circulatory system.

An advantage of the catheters described in U.S. Patent Nos. 5,584,803 and 5,682,906 is that direct access to the heart through a median sternotomy is not required. Elimination of the median sternotomy reduces the pain and trauma to the patient as compared to conventional open chest surgery. In conventional open chest surgery, an external cross-clamp, which is introduced through the large opening in the chest, is used to occlude the ascending aorta. The catheter systems described in U.S. Patent Nos. 5,584,803 and 5,682,906 provide an aortic occlusion catheter which replaces the conventional external cross-clamp for occluding the ascending aorta. An advantage of the aortic occlusion catheter is that the aorta is not crushed or distorted which may reduce the release of emboli thereby reducing stroke incidents. Various aortic occlusion catheters are described in U.S. Patent Application Serial No. 08/782,113 to Corvi et al. which is hereby incorporated by reference.

Blood is withdrawn from the patient through a venous cannula and directed to a bypass system which oxygenates and pumps the oxygenated blood back to the patient through an arterial cannula. A vent catheter vents blood from the pulmonary

artery thereby assisting the venous cannula in withdrawing blood and preventing blood and other fluids from pooling in the heart. The vent catheter also serves as a diagnostic tool since high blood flows through the vent may indicate improper positioning of the venous cannula.

An object of the present invention is to provide improved multi-lumen catheters and methods of use. The following description of the invention is directed to various specific catheters for the purpose of illustrating specific procedures in which the catheters of the present invention are useful, however, the multi-lumen catheters of the present invention may be used for other procedures and in other parts of the body.

SUMMARY OF THE INVENTION

In accordance with the objects of the present invention a method of constructing a multi-lumen catheter is provided. The multi-lumen catheter has a first tube having a first lumen and a first wall. The multi-lumen catheter also has a second tube having a second lumen and a second wall. The second tube is positioned in the first tube and is unattached to the first wall for a distance of at least three inches, more preferably at least five and most preferably at least 10 inches. A cap is attached to the end of the first tube and has a first opening which receives the second tube. An advantage of passing the first tube through the second tube is that the overall flexibility of the catheter is enhanced. Conventional multi-lumen catheters, such as extruded catheters, have internal walls separating the lumens which increases the stiffness of the catheter. The multi-lumen catheter of the present invention has good flexibility as compared to conventional, extruded multi-lumen catheters which is important when passing the catheter through the patient's vascular system. Flexibility is particularly important when the catheter uses flow-directing features for placement.

The present invention is also directed to a method of accessing a patient's pulmonary artery. A pulmonary artery catheter is inserted into a peripheral vein. The catheter has a first lumen, a second lumen, and an expandable member movable from a collapsed position to an expanded position. The first lumen has a first outer wall and the second lumen has a second outer wall. The second outer wall passes inside the first outer wall and is unattached to the first outer wall for at least three inches. The expandable member, which is preferably a balloon, is expanded after the

expandable member has been passed into the right atrium. The expandable member is then used to flow-direct the catheter through the tricuspid and pulmonary valves and into the pulmonary artery. In a preferred method of the present invention, blood is withdrawn through the pulmonary artery catheter and directed to a bypass system.

The present invention is also directed to a method of occluding a patient's ascending aorta and returning blood from a bypass system. An aortic occlusion catheter is inserted into a peripheral artery such as the femoral or subclavian arteries. The aortic occlusion catheter has a first lumen, a second lumen, and an occluding member movable between a collapsed position and an expanded position. The second lumen passes through the first lumen and is unattached to the lumen for at least three inches, more preferably at least five and most preferably at least ten inches. The first lumen is enclosed by a first wall and the second lumen is enclosed by a second wall with the first wall being attached to the second wall at a distal end of the first lumen. The aortic occlusion catheter is advanced into the patient until the occluding member is positioned in the ascending aorta. The occluding member, which is preferably a balloon, is then expanded to occlude the ascending aorta. Oxygenated blood from a bypass system is introduced into the patient through the first lumen. In a preferred method, the second lumen is coupled to a source of cardioplegic fluid and cardioplegic fluid is infused into the patient to arrest the patient's heart in preparation for surgery.

These and other objects and advantages of the present invention will become apparent with the following description, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a catheter system having a venous cannula, an aortic occlusion catheter and a pulmonary artery venting catheter;

Fig. 2 shows the pulmonary artery venting catheter of Fig. 1;

Fig. 3 is a cross-sectional view of a distal end of the catheter of Fig. 2;

Fig. 4 is a cross-sectional view of the distal end of the vent catheter of Fig. 3 along line A-A;

Fig. 5 is a cross-sectional view of the distal end of the vent catheter of Fig. 3 along line B-B;

Fig. 6 is an isometric view illustrating the elements used to form the distal end of Fig. 3;

Fig. 7 is a cross-sectional view of the proximal end of the catheter of Figs. 2-6;

Fig. 8 is an isometric view illustrating the elements used to form the proximal end of Fig. 6;

Fig. 9 shows the aortic occlusion catheter;

Fig. 10 is a cross-sectional view of the aortic occlusion catheter of Fig. 9 along line C-C;

Fig. 11 is a partial cross-sectional view of a proximal end of the aortic occlusion catheter of Fig. 9 around line D-D; and

Fig. 12 is a partial cross-sectional view of the distal end of the blood flow lumen of the aortic occlusion catheter of Fig. 9 around line E-E.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Fig. 1, a catheter system 2 for arresting a patient's heart and maintaining the patient on bypass support is shown. A venous cannula 4 withdraws blood from the patient and directs the blood to a bypass system 6 which preferably includes a pump and oxygenator, however, the patient's own lungs may also be used to oxygenate the blood. A catheter 8 cooperates with the venous cannula 4 to withdraw blood from the patient and direct the blood to the bypass system 6. The catheter 8 has a lumen 10 through which blood is withdrawn from the pulmonary artery and directed to the bypass system 6. The catheter 8 also has a balloon 12 for flow-directed placement into the pulmonary artery as will be described below. The catheter 8 is introduced through a conventional introducer sheath 15.

Another catheter 14 is used to return blood to the patient from the bypass system 6. The catheter 14 has a first lumen 16 coupled to the bypass system 6 to return oxygenated blood to the patient. The catheter 14 has a second lumen 18 coupled to a source of cardioplegic fluid 20 and a third lumen 22 coupled to a pressure sensor 24 for measuring pressure in the ascending aorta. Cardioplegic fluid is delivered through the second lumen 18 to arrest the patient's heart in preparation for surgery on the heart and circulatory system. The catheter 14 also has an occluding member 26 for occluding the patient's ascending aorta. The occluding member 26 is preferably a balloon which is coupled to an inflation lumen 28 for inflating the

balloon from a source of inflation fluid 30 such as a syringe filled with saline. The catheter 14 is described in greater detail below in connection with Figs. 9-12.

Referring to Fig. 2, the catheter 8 for venting the pulmonary artery is shown. The lumen 10 terminates at a barbed connector covered by a removable cap 32. After removing the cap 32, the barbed connector is coupled to a vacuum relief valve 34 with tubing 36. The vacuum relief valve 34 is, in turn, coupled to the bypass system 6 (see Fig. 1) with tubing 38. A balloon inflation lumen 40 is coupled to a syringe 42 filled with air or carbon dioxide for inflating the balloon 12. The balloon 12 may be made of any suitable material and is preferably made of polyurethane having a wall thickness of about 0.002 inch. The balloon 12 preferably inflates to a diameter of at least 0.3 inch and more preferably at least 0.4 inch. If the balloon 12 is designed to occlude a vessel, such as a pulmonary artery, the balloon 12 preferably inflates to a diameter of at least 0.6 inch and more preferably at least 0.7 inch.

A distal portion of the catheter 8 is shaped to facilitate placement of the catheter 8 in the pulmonary artery when introduced through the internal jugular or subclavian vein. The distal portion may also take any other shape which facilitates introduction through another blood vessel such as the femoral vein. The distal portion of the catheter 8 has a radius of curvature of about 1.4-1.6 inches and subtends an angle of about 150-170 degrees. A contamination guard 44 prevents contamination of the catheter 8. The contamination guard 44 has a connector 46 which engages a connector on the introducer sheath 15 (see Fig. 1).

Referring to Figs. 3-6, the catheter 8 has an outer wall 48 which encloses the lumen 10. An opening 50 at the distal end is fluidly coupled to the lumen 10 for withdrawing fluid from or infusing fluid into the patient through the lumen 10. A number of holes 52, preferably eight, in the outer wall 48 enhance flow into and out of the lumen 10. An inflation hole 54 couples the interior of the balloon 12 to the inflation lumen 40. The lumen 10 preferably has a cross-sectional area of between 0.003 inches^2 and 0.013 inches^2 and more preferably 0.005 inches^2 and 0.008 inches^2. The inflation lumen 40 preferably has a cross-sectional area of between 5×10^{-5} inches^2 and 2×10^{-4} inches^2 and more preferably between 8×10^{-5} inches^2 and 1×10^{-4} inches^2. Alternatively, the lumen 10 is preferably at least twenty times, more preferably at least forty times, and most preferably at least 60 times larger than the inflation lumen 40.

Referring to Figs. 3 and 5, the inflation lumen 40 passes through the lumen 10 and has a wall 56 which is not attached to the outer wall 48. An advantage of separating the inflation lumen 48 from the lumen 10 is that the catheter 8 is very flexible. Many conventional multi-lumen catheters, such as multi-lumen extruded catheters, are somewhat rigid since the internal walls forming the multi-lumen structure add stiffness as compared to a simple, single-lumen tube. By passing the inflation lumen 40 through the lumen 10, the catheter 8 provides multiple lumens without sacrificing flexibility as compared to a multi-lumen structure. Flexibility is particularly important when using flow-directed placement since the catheter 8 must be flexible enough to be displaced by the flow-directing balloon 12. The inflation lumen 40 preferably extends through the lumen 10 for an unattached length of at least three inches, more preferably at least five and most preferably at least ten inches. The unattached length is preferably near the distal end of the catheter in that the unattached length begins no more than 2 inches and more preferably no more than 1 inch from a distal tip 57 of the catheter 8.

Referring to Figs. 3 and 6, the method of manufacturing the distal end of the catheter 8 is shown. The outer wall 48 includes a shaft 58 and an extension 60. The extension 60 has the holes 52 therein to enhance flow into and out of the lumen 10. The shaft 58 is preferably made of polyurethane having a wall thickness of between 0.017 inch and 0.021 inch and more preferably between 0.018 inch and 0.020 inch. A helical reinforcing element 62, which is preferably a stainless steel wire, is embedded in the shaft 58 to reinforce the shaft 58. The reinforcing element 62 has a thickness of 0.003 inch and a width of 0.012 inch. Although the reinforcing element 62 has a rectangular cross-sectional shape, the reinforcing element 62 may have any other cross-sectional shape such as circular. The shaft 58 is formed by wrapping the reinforcing element 62 around a tube of polyurethane having a thickness of 0.0030 inch. Another polyurethane tube having a thickness 0.0035 inch is placed over the reinforcing element 62. A shrink tube is then placed over the entire structure and the structure is heated to form an integrated structure. The shrink tube is then removed. The reinforced shaft 58 preferably has a length of at least 62 cm and more preferably at least 72 cm. The extension 60 and shaft 58 are then bonded together preferably with thermal jaws which also apply compression during cooling.

The distal end of the cap 64 is placed in a mold with a blocker in the first lumen 68. The mold is shaped to give the distal end of the catheter 8 the rounded, atraumatic shape of Fig. 3. A soft tip 70 is then attached to the distal end of the cap 64. The soft tip 70 is preferably made of polyurethane having a thickness of 0.011 inch. The soft tip 70 is placed over the distal end of the cap 64, a shrink tube is placed over the soft tip 70 and the soft tip 70 is then heated to melt and fuse the tip 70 to the cap 64. The soft tip 70 conforms generally to the curved, atraumatic shape of the cap 64 as shown in Fig. 3. The cap 64 is also notched to form the inflation opening 54.

The inflation lumen 40 is bonded to the cap 64 at a proximal location 65. Blockers (not shown) are inserted into the lumen 10 and inflation lumen 40 to prevent the lumens 10, 40 from collapsing when heated. The cap 64 and inflation lumen 40 are then placed in a hot box to fuse the inflation lumen 40 to the cap 64 at the proximal location. Referring to Fig. 4, the inflation lumen 40 is only bonded to the cap 64 at the proximal location.

The inflation lumen 40 and the outer wall 48 are attached to a cap 64. The cap 64 has a first lumen 66, which receives the inflation lumen 40, and a second lumen 68 which is coupled to and serves as an extension of the lumen 10.

The cap 64 is positioned inside the extension 60 and a shrink tube (not shown) is placed over the interface between the cap 64 and extension 60. Thermal jaws are closed over the shrink tube and the structure is heated to bond the cap 64 to the extension 60. The balloon 12 is then bonded to the shaft 48 by bonding the distal end first, inverting the balloon 12, then bonding the proximal end of the balloon to the shaft 48. The distal end of the catheter 8 is then given the curved shape shown in Fig. 2.

Referring to Figs. 7 and 8, exploded and cross-sectional views of the proximal end of the catheter 8 are shown. A proximal end of the shaft 58 is heat bonded to a proximal extension 72. A hole 74 is formed in the proximal extension 72 through which the inflation lumen 40 passes. A lumen lead 76 is passed over the inflation lumen 40. The lumen lead 76 has a beveled end 78 which contacts the proximal extension 72 so that the lumen leads 76 extends from the proximal extension 72 at an angle as shown in Fig. 2. A shrink tube is placed over the lumen lead 76 and the proximal extension 72 and a blocker (not shown) is positioned in the inflation lumen 40 and proximal extension 72. The lumen lead 76, proximal extension 72 and

inflation lumen 40 are then heated so that the lumen lead 76 and proximal extension 72 fuse together and bond to the inflation lumen 40 as shown in Fig. 7. The lumen lead 76 and the proximal extension 72 are then attached to conventional connectors. The extension 72 is preferably a tube of polyurethane having a thickness of 0.011 inch. The lumen lead 76 is preferably a polyurethane tube having a thickness of 0.015 inch.

The catheter 8 is preferably configured to withdraw blood at a rate of at least 50 ml/min, and more preferably at least 125 ml/min. At the same time, the pressure of the blood withdrawn through lumen, at temperatures ranging from about 4°C to 40°C, should be no lower than -300 mmHg, and preferably no lower than -150 mmHg. In an exemplary embodiment, the lumen preferably has a diameter ID of at least about 2.0 mm, and usually about 2.2-3.0 mm, thus having a cross-sectional area of at least about 4.0 mm^2, and usually 4.2-9.0 mm^2.

The catheter 8 is introduced percutaneously or by surgical cut-down into a peripheral vein such as the internal jugular, subclavian or femoral vein. The catheter 8 is preferably introduced percutaneously through the 9 French introducer sheath 15 in the internal jugular or subclavian vein. Once the sheath 15 is in place, the balloon 12 is deflated and the catheter 8 is advanced until the balloon 12 is beyond a hemostasis valve in the sheath 15. The connector 46 on the contamination guard 44 is coupled to a connector on the introducer sheath 15 to lock the contamination guard in place and prevent contamination of the catheter 8. The catheter 8 is advanced until the balloon 12 is in the right atrium. The balloon 12 is then inflated so that the balloon 12 will flow-direct the catheter through the tricuspid and pulmonary valves and into the pulmonary artery. The balloon 12 is then deflated and the catheter 8 is ready for withdrawing blood from the pulmonary artery. Although a specific use of the catheter 8 described herein is for withdrawing blood from the pulmonary artery, the catheter 8 may also be used in any other part of the patient for any other purpose. For example, the catheter 8 may be used in the pulmonary artery for cardiac output monitoring via thermodilution, measurement of pressure in right atrium, right ventricle and pulmonary artery, wedge pressure and transvenous pacing. Such additional procedures may be performed by adding another lumen, such as a pressure lumen, which floats through the lumen 10 like the inflation lumen 40. The cap 64 would simply include another through-lumen 68 which would be coupled to the pressure

lumen. Thus, although the catheter 8 includes only the lumen 10 and inflation lumen 40 the catheter 8 may also have other lumens for other uses. Finally, the catheter 8 is described in connection with catheter system 2, however, the catheter 8 may be used with any other catheters without departing from the scope of the invention. For example, the catheter 8 may be used with an arterial cannula and an aortic occlusion catheter as described in U.S Patent Application Serial No. 08/782,113 by Corvi et al., filed January 13, 1997.

Referring now to Fig. 9, the catheter 14 for occluding the ascending aorta and delivering oxygenated blood to the patient from the bypass system 6 is shown. The catheter 14 has an occluding member 26, which is preferably a balloon, for occluding the ascending aorta. When the occluding member 26 is a balloon, the inflation lumen 28 is coupled to the source of inflation fluid 30 (see Fig. 1) which is typically a syringe filled with saline. A distal portion 83 of the catheter 14 is shaped to facilitate placement of the catheter 14 in the ascending aorta when introduced through the femoral artery. The occluding member 26 may be made of any suitable material and is preferably made of polyurethane having a wall thickness of 0.005 to 0.006 inch. The occluding member 26 preferably expands to a diameter of at least 1.0 inch and more preferably at least 1.5 inches.

Referring to Figs. 10-12, the catheter 14 has an outer wall 82 which encloses a body 84. The outer wall 82 is relatively stiff and is not collapsible so that the integrity of the first lumen 16 is maintained even when the outer wall 82 passes through tortuous vessels. The body 84 has the inflation lumen 28 and second and third lumens 18, 22. The body 84 passes through the first lumen 16 and is unattached to the first lumen 16 for at least three inches, more preferably at least five inches and most preferably at least 10 inches. The lumens 18, 22, 28 are not attached to the outer wall 82 which enhances the flexibility of the catheter 14. As discussed above, multi-lumen catheters can become somewhat rigid due to the walls separating the lumens. By decoupling the lumens 18, 22, 28 from the outer wall 82 the multi-lumen catheter retains flexibility. The body 84 may be formed in any conventional manner and is preferably formed in the manner described in U.S. Patent Application Serial No. 08/782,113 filed January 13, 1997 by inventors Corvi et al. A difference between the body 84 and the catheters described in U.S. Patent Application Serial No. 08/782,113 is that the body 85 has a longitudinal reinforcing element 86. The longitudinal

reinforcing element 86 reduces elongation of the body 84 when tensile forces are exerted on the body 84.

Referring to Fig. 12, a cross-sectional view of the distal end of the catheter 14 is shown. The outer wall 82 includes a shaft 86 and an extension 88. The outer wall 82 is preferably long enough to reach the ascending aorta from a peripheral artery, such as the femoral, axillary or subclavian arteries, and has a length of at least 19 inches and more preferably at least 39 inches. The shaft 88 is preferably made of urethane having a wall thickness of 0.016 inch. A helical reinforcing element 90, which is preferably a stainless steel wire, is embedded in the shaft 86 to reinforce the shaft 86. The reinforcing element 90 has a thickness of about 0.006 inch and a width of about 0.010 inch. Although the reinforcing element 90 has a rectangular cross-sectional shape, the reinforcing element 90 may have any other cross-sectional shape such as circular. The shaft 86 is formed by wrapping the reinforcing element 90 around a tube of urethane having a thickness of about 0.013 inch. Another urethane tube having a thickness of 0.003 inch is then placed over the reinforcing element 90. A shrink tube is then placed over the entire structure and the structure is heated to form the shaft. The shrink tube is then removed. The extension 88 and shaft 86 are then bonded together. Although it is preferred to couple the lumens 18, 22, 28 together in the body 84, the lumens 18, 22, 28 may also be structurally separated from each other similar to the catheter 8 described above. Thus, the lumens 18, 28 may be positioned within the lumen 20 similar to catheter 8 or each of the lumens 18, 20, 22 may pass independently through the first lumen 16 without departing from the scope of the present invention. The proximal end of the shaft 86 is attached to a proximal extension 87 which is formed in a manner similar to the proximal extension 72 of Figs. 7 and 8.

The catheter 14 is preferably configured to deliver blood at a rate of at least 4.7 ml/min, and more preferably at least 5.9 ml/min. At the same time, the pressure of the blood delivered through main lumen, at temperatures ranging from about 4°C to 40°C, should be no higher than 300 mmHg, and preferably no higher than 200 mmHg. In an exemplary embodiment, the main lumen preferably has a diameter ID of at least about 0.236 inch, and usually about 0.269 inch, thus having a cross-sectional area of at least about 0.0437 inches^2, and usually 0.0568 inches^2.

A method of using the catheter 14 is now described. The catheter 14 is introduced into the patient through a peripheral artery such as the subclaivian or femoral arteries. The catheter 14 is advanced until the occluding member 26 is positioned in the ascending aorta. The occluding member 26 is expanded to occlude the ascending aorta and cardioplegic fluid is delivered to arrest the patient's heart. Blood is withdrawn through the venous cannula 4 and then returned to the patient through the first lumen 16 in the catheter 14.

While the present invention has been described herein in terms of certain preferred embodiments, it will be apparent to one of ordinary skill in the art that many modifications and improvements can be made to the invention without departing from the scope thereof. For example, the outer wall may have more openings therein for enhanced blood flow out of the lumen or the occluding member may be a mechanically actuated member.

WHAT IS CLAIMED IS:

1. A method of endovascularly accessing a pulmonary artery comprising the steps of:

inserting a pulmonary artery catheter into a peripheral vein, the catheter having a first lumen, a second lumen, and an expandable member movable from a collapsed position to an expanded position, the first lumen having a first outer wall and the second lumen having a second outer wall, the second outer wall being unattached to the first outer wall and being positioned within the first outer wall for a distance of at least three inches;

expanding the expandable member to the expanded position after the inserting step;

passing the distal end of the catheter through the tricuspid and pulmonary valves so that at least a portion of the catheter is positioned in the pulmonary artery.

2. The method of claim 1, wherein:

the expanding step is carried out so that the catheter is flow-directed with the expandable member directing the catheter in the direction of blood flow.

3. The method of claim 1, further comprising the step of:

withdrawing blood from the pulmonary artery through the first lumen.

4. The method of claim 1, wherein:

the inserting step is carried out with the expandable member being an inflatable balloon, the balloon being coupled to the second lumen.

5. The method of claim 4, wherein:

the inserting step is carried out with the balloon expanding to an outer dimension of at least 0.4 inches.

6. The method of claim 4, wherein:

the inserting step is carried out with the distance being at least five inches.

7. The method of claim 1, wherein:

the inserting step is carried out with the distance being at least ten inches.

8. The method of claim 1, wherein:

the inserting step is carried out with the first lumen having a cross-sectional area of between 0.003 inches^2 and 0.013 inches^2.

9. The method of claim 8, wherein:

the inserting step is carried out with the first lumen having a cross-sectional area of between 0.005 inches^2 and 0.008 inches^2.

10. The method of claim 1, wherein:

the inserting step is carried out with the first outer wall having a helical reinforcing member embedded therein.

11. The method of claim 1, wherein:

the inserting step is carried out with the first lumen having a cross-sectional area which is at least 20 times larger than the cross-sectional area of the second lumen.

12. A multi-lumen catheter, comprising:

a first tube having a first lumen and a first wall;

a second tube having a second lumen and a second wall, the second tube being positioned in the first tube and being unattached to the first wall for a distance of at least three inches; and

a cap attached to an end of the first tube, the cap having a first opening which receives the second tube.

13. The catheter of claim 12, wherein:

the cap has a hole passing through the member, the hole being fluidly coupled the first lumen.

14. The catheter of claim 12, wherein:
the first wall has at least one hole therein leading to the first lumen.

15. The catheter of claim 12, further comprising:
a balloon;
the second lumen being coupled to the balloon for inflating the balloon.

16. The catheter of claim 12, wherein:
the first lumen has a cross-sectional area at least forty times larger than a cross-sectional area of the second lumen.

17. A method of occluding a patient's ascending aorta and delivering cardioplegic fluid to the patient, comprising the steps of:
providing an aortic occlusion catheter having a first lumen, a second lumen, and an occluding member movable between a collapsed position and an expanded position, the second lumen passing through the first lumen and being unattached to the blood flow lumen for a distance of at least three inches, the first lumen being enclosed by a first wall and the second lumen being enclosed by a second wall, the first wall being attached to the second wall at a distal end of the first lumen;
introducing the aortic occlusion catheter into a peripheral artery with the occluding member in the collapsed position;
positioning the occluding member in the ascending aorta;
expanding the occluding member after the positioning step;
coupling the first lumen to a source of oxygenated blood; and
infusing oxygenated blood into the patient through the first lumen.

18. The method of claim 17, further comprising the steps of:
coupling the second lumen to a source of cardioplegic fluid; and
infusing cardioplegic fluid into the patient through the second lumen.

19. The method of claim 17, further comprising the steps of:
coupling the second lumen to a source of inflation fluid;

the providing step is carried out with the occluding member being a balloon;

the expanding step being carried out by inflating the balloon with the source of inflation fluid from the second lumen.

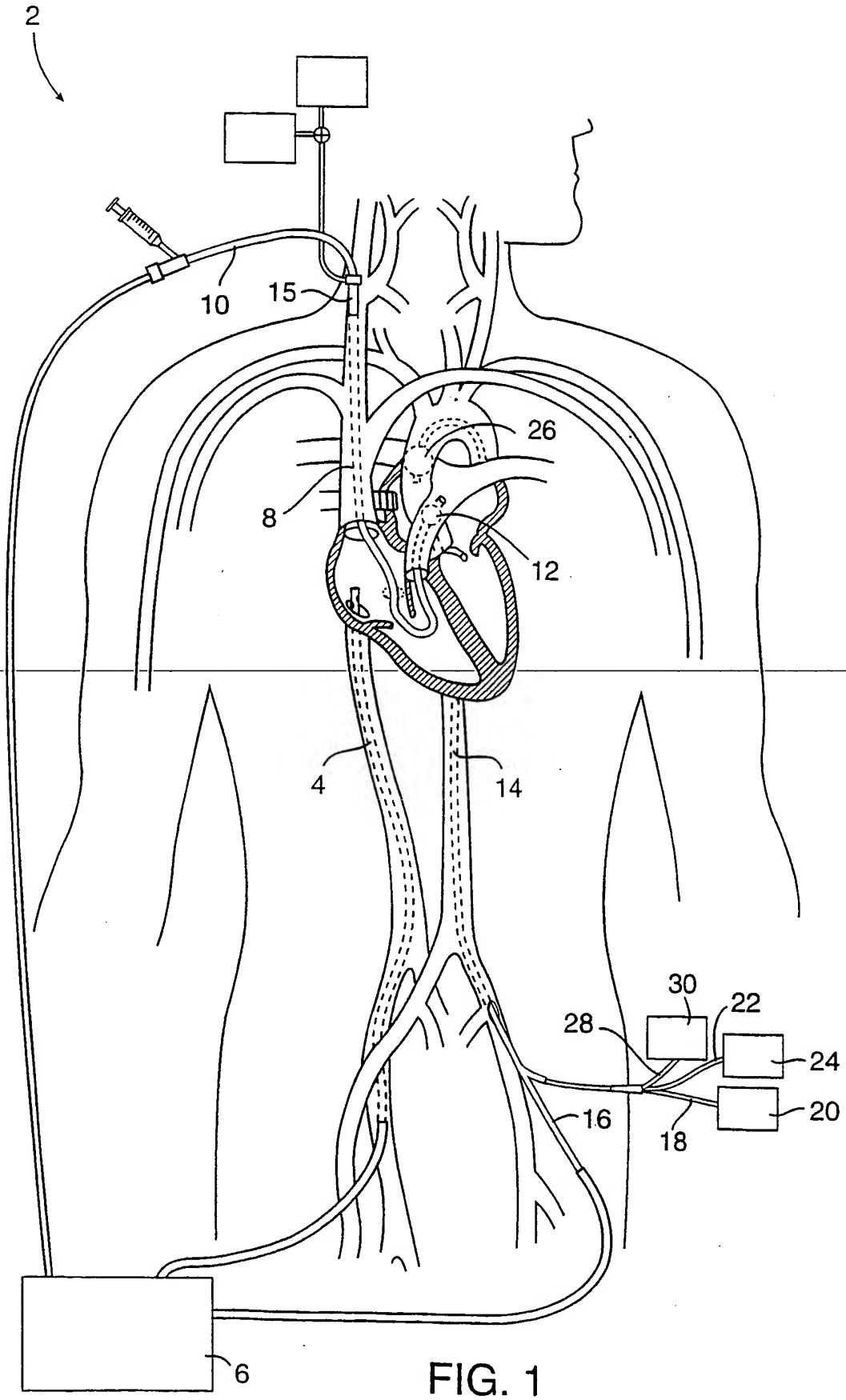


FIG. 1

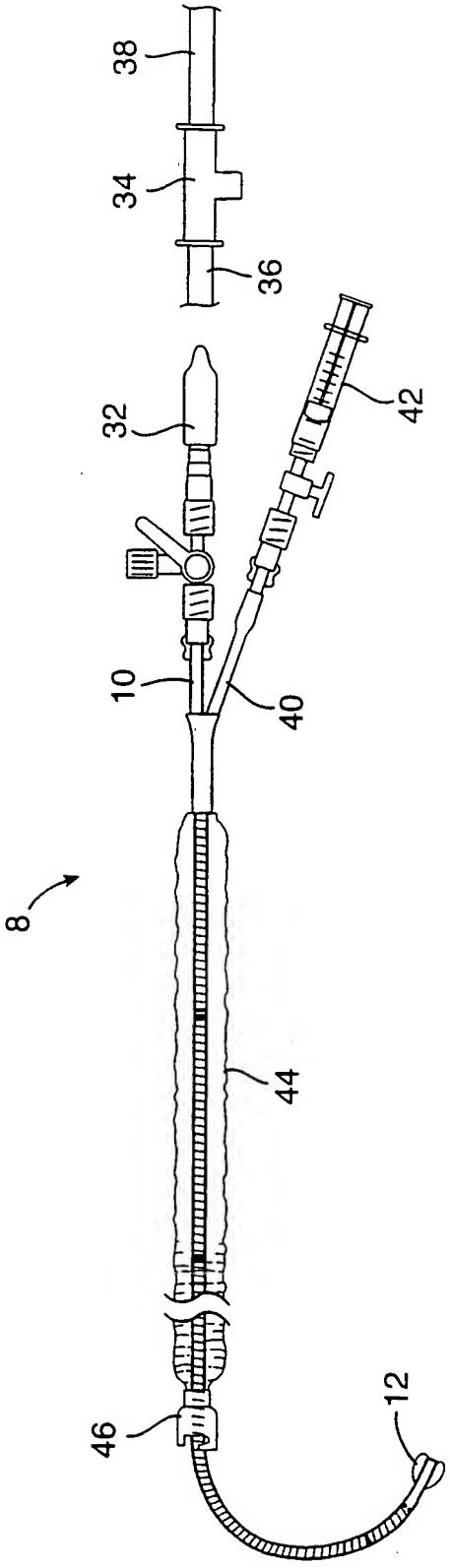


FIG. 2

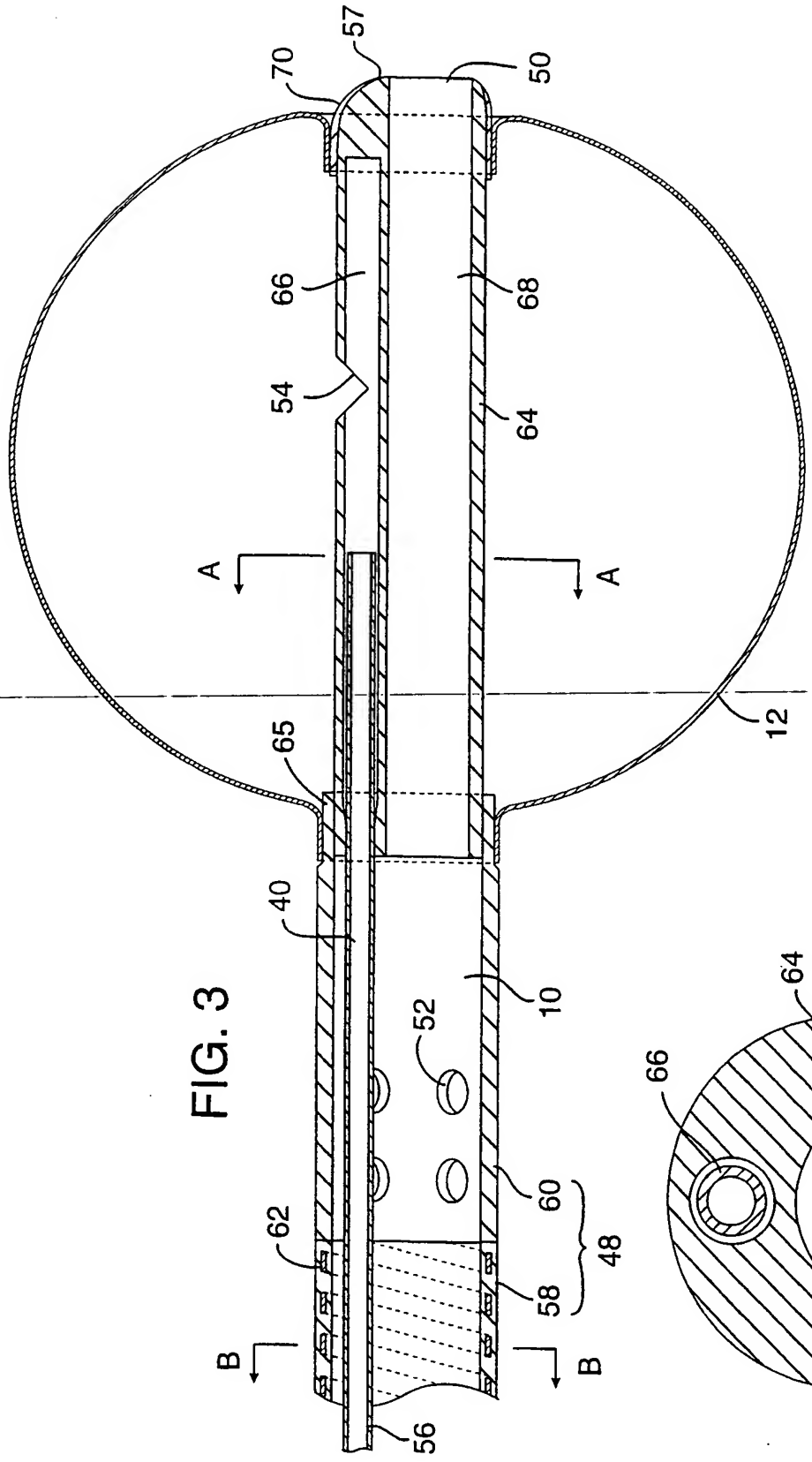


FIG. 3

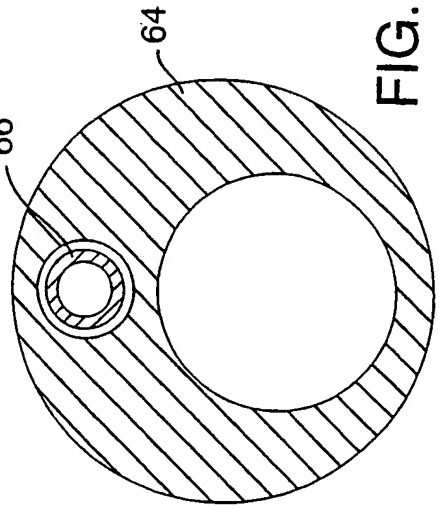


FIG. 4

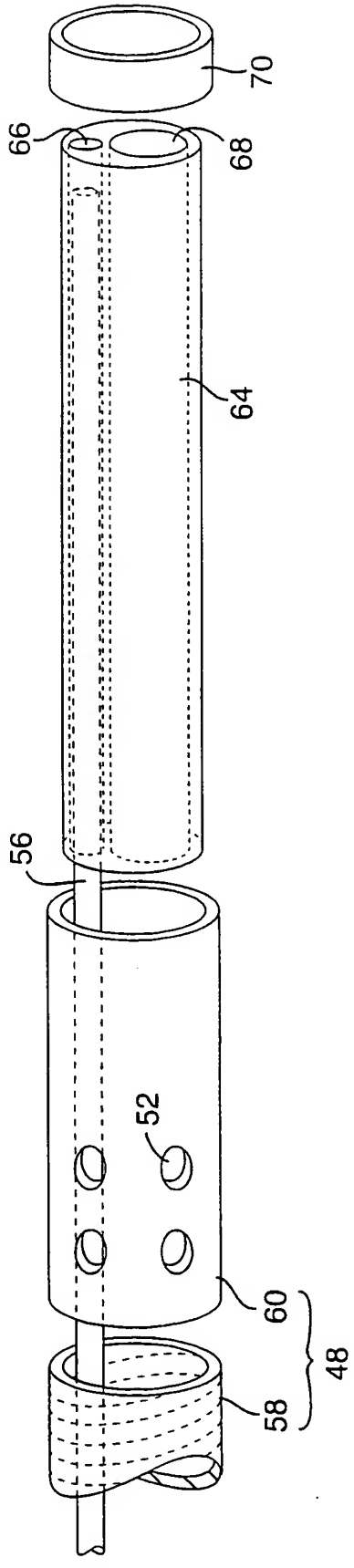


FIG. 6

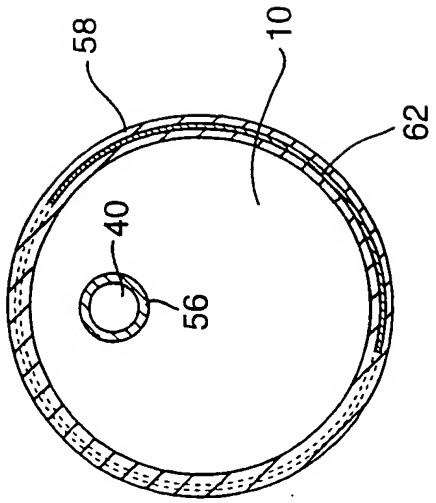


FIG. 5

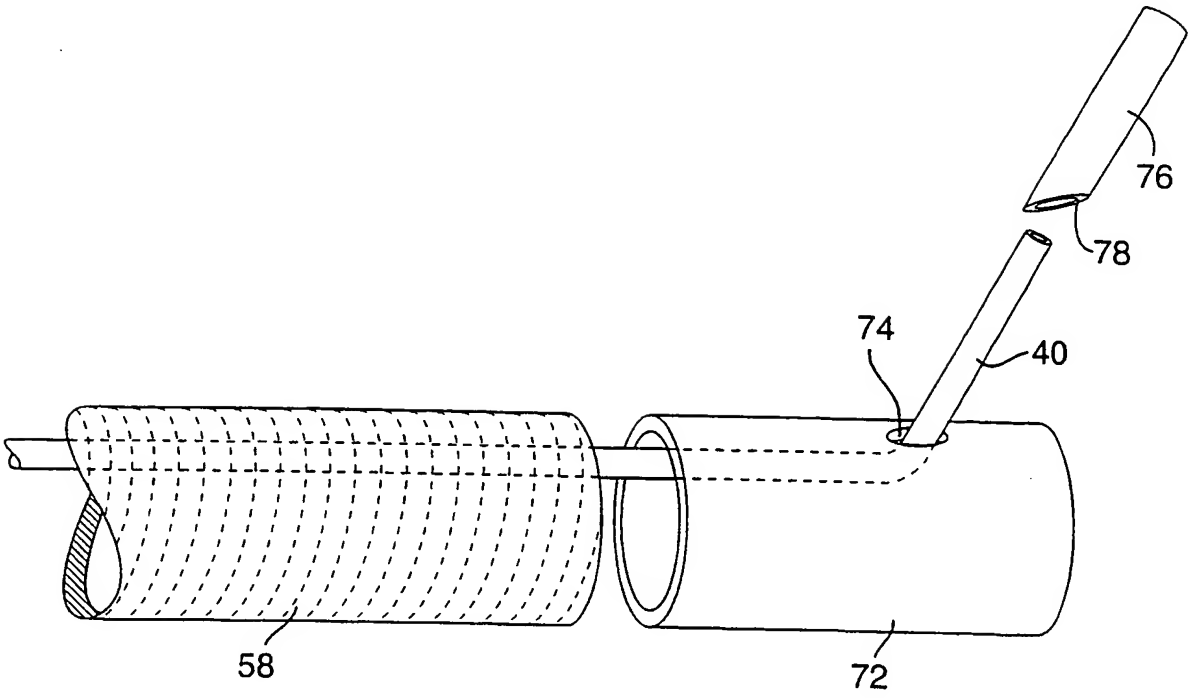


FIG. 8

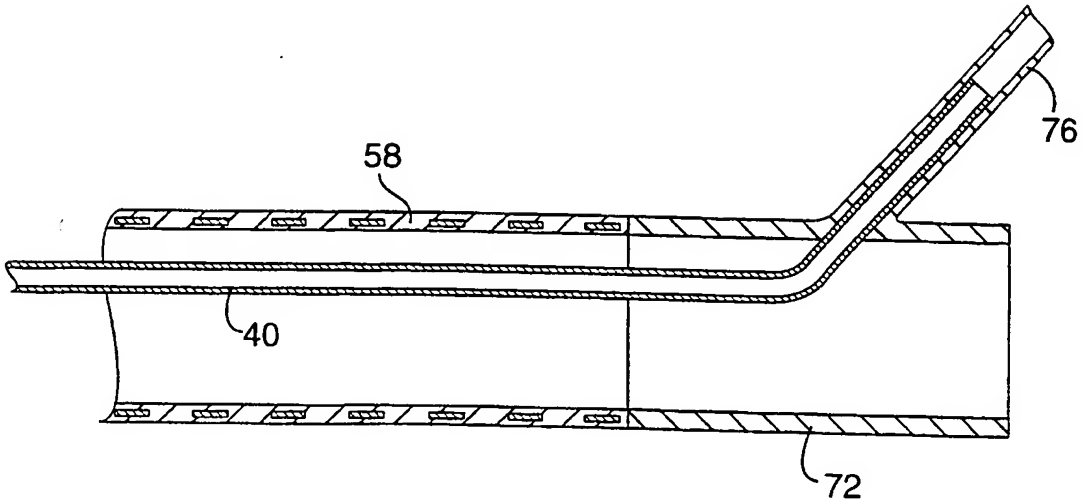


FIG. 7

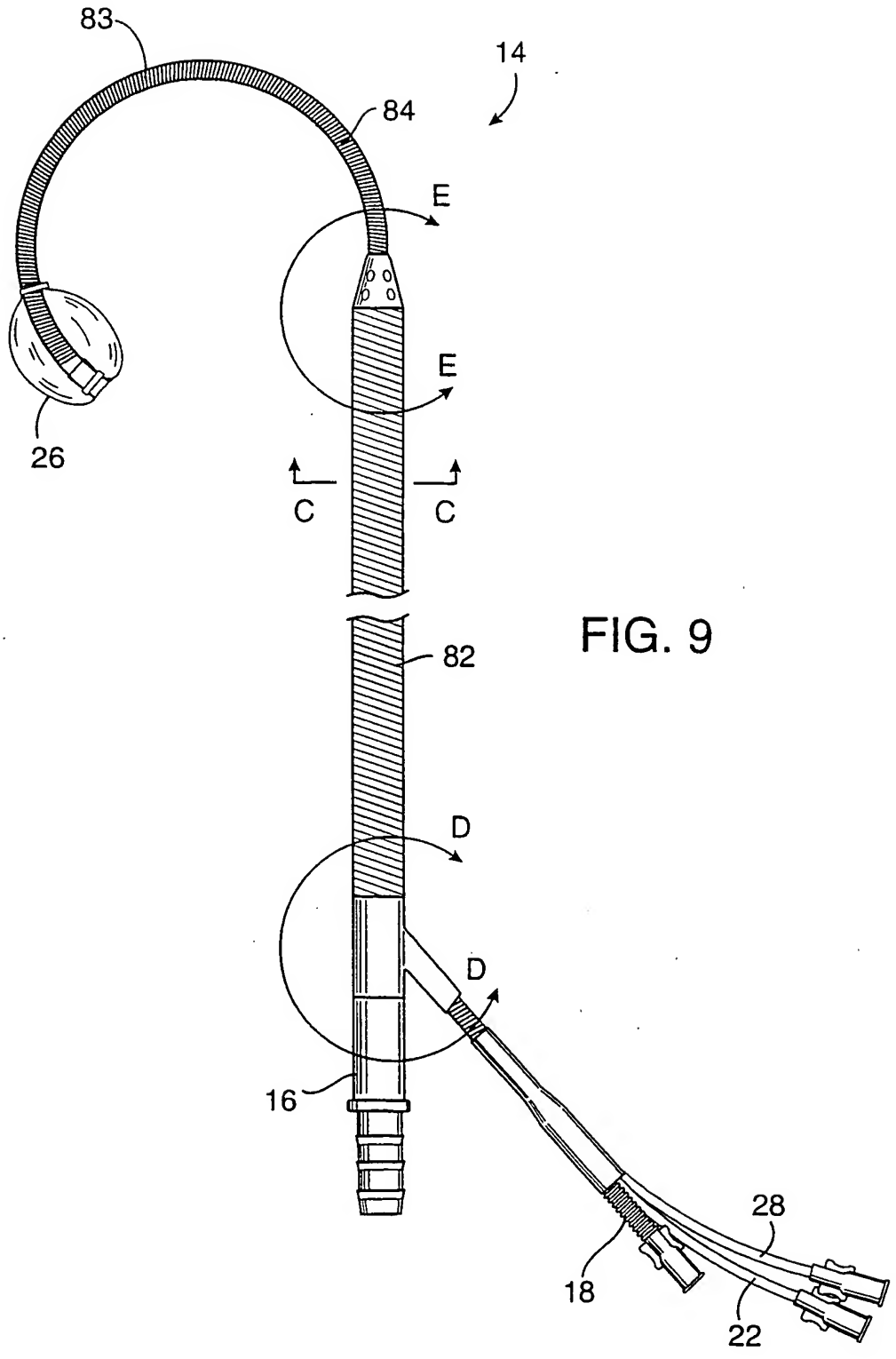


FIG. 9

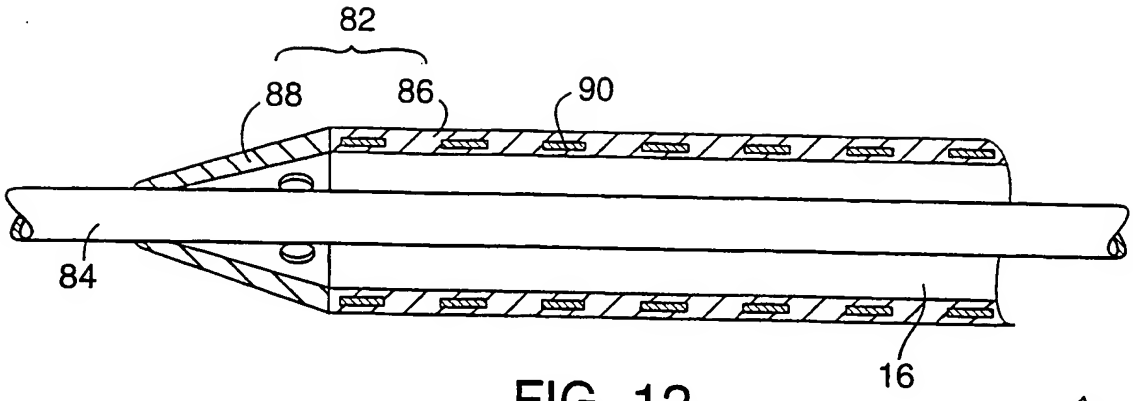


FIG. 12

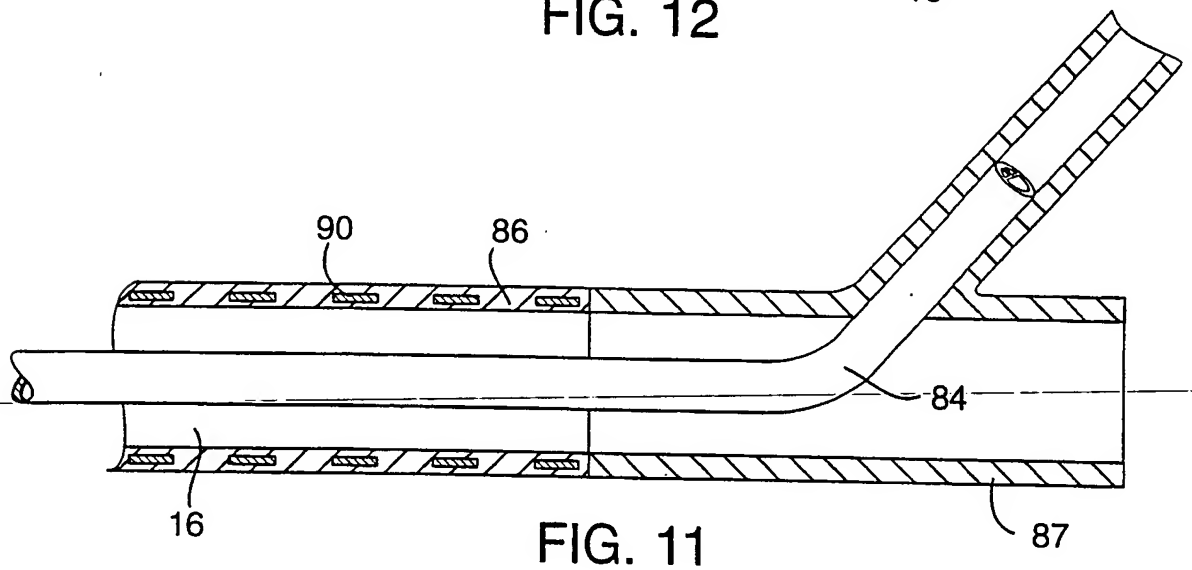


FIG. 11

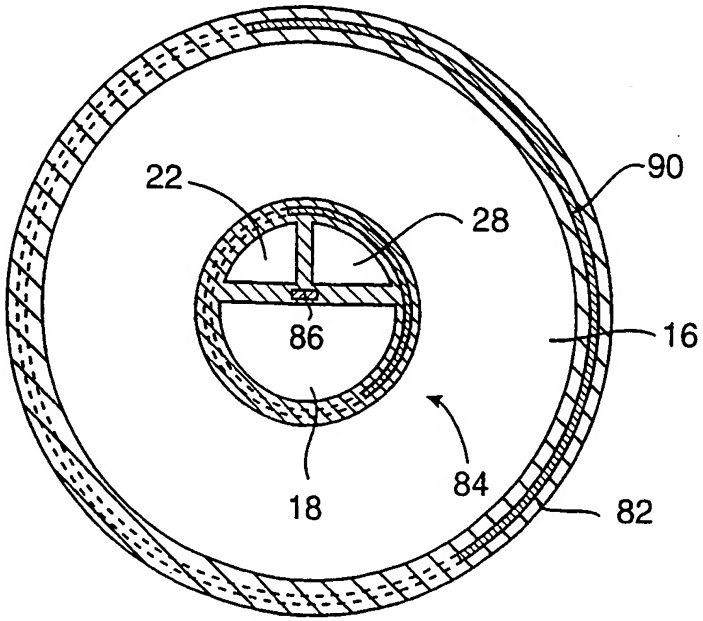


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/10180

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) : A61M 1/00, 29/00, 31/00
US CL : 604/96, 509, 540
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/96, 102, 506-509, 540, 914, 921; 606/192, 194

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,684,363 A (ARI et al.) 04 August 1987, see Fig, 5.	12-15
---		---
Y		1-11, 16-19
X	US 4,299,227 A (LINCOFF) 10 November 1981, Figs. 3-5.	12-15
---		---
Y		1-11, 16-19
Y	US 5,584,803 A (STEVENS et al.) 17 December 1996, Abstract.	1-11, 17-19
X	US 5,421,826 A (CROCKER et al.) 06 June 1995, Figs. 1-10.	12-15
---		---
Y		1-11, 16-19

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents
"A" Document defining the general state of the art which is not considered to be of particular relevance
"E" Earlier document published on or after the international filing date
"L" Document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" Document referring to an oral disclosure, use, exhibition or other means
"P" Document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" Document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" Document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" Document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 JUNE 1999	02 AUG 1999
Name and mailing address of the ISA US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LOAN H. THANH Telephone No. (703) 305-0038

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/10180

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, P	US 5,827,220 A (RUNGE) 27 October 1998, entire document.	1-19
A	US 5,738,649 A (MACOVIAK) 14 April 1998, entire patent.	1-19
A	US 5,718,680 A (KRAUS et al.) 17 February 1998, entire patent.	1-19
A	US 5,588,965 A (BURTON et al.) 31 December 1996, figures.	12-15
A	US 5,002,556 A (ISHIDA et al.) 26 March 1991, figures.	12-16
A	US 5,002,556 A (Ishida et al.) 26 March 1991, See figures.	12-16